K003195

DEC 1 3 2000

GREER LABORATORIES, INC.™

POST OFFICE BOX 800 • 639 NUWAY CIRCLE • LENOIR, NORTH CAROLINA 28645 U.S.A.
PHONE: 828/754-5327 or 800/438-0088 • FAX: 828/754-5320
www.greerlabs.com

510(k) SUMMARY

Submitter:	Greer Laboratories, Inc. 639 Nuway Circle NE Lenoir, NC 28645 phone: (828) 754-5327 fax: (828) 754-5320
Contact:	Gerald Friesen, PharmD Vice President, Quality
Date:	10 October, 2000
Device Name:	GreerTRACK Skin Testing System
Common/ Classification Name:	System, Delivery, Allergen and Vaccine
Predicate Device:	GreerPICK (DermaPICK) Skin Test Device
Description:	The device system is comprised of both single-use and reusable components. The device includes: 1) The Track – a sterile, single-use, injection molded, plastic piece with four sites having four tines each, intended to deliver the allergens into the epicutaneous layer of the skin. The Track is injection molded from a thermoplastic polymer. The material has been tested to meet USP Class VI performance criteria for biocompatibility. The Tracks are packaged in a PETG tray sealed with a tyvek lid, eight Tracks per tray. 2) A reusable Handle designed to "pick-up" and hold one or two Tracks. The Handle is constructed of a plastic body, stainless steel metal screws, and spring, and a machined, extruded metal trigger/latch mechanism designed to engage and hold the Tracks. 3) A reusable polystyrene plastic Loading Tray designed to hold one Handle with attached Tracks, and eight vials of allergen extracts.
Intended Use:	Prick/puncture application of multiple allergen extracts in the performance of skin testing for immediate type hypersensitivity reactions in those individuals suspected of having allergies.

Technological Charateristics: Comparison to Predicate Device

	TARGET POPULATION
GreerTRACK	The device is intended for use by medical professionals in the testing of individuals suspected of having allergies.
GreerPICK	The device is intended for use by medical professionals in the testing of individuals suspected of having allergies.
	DESIGN
GreerTRACK	The device is designed to apply 8 allergen/control extracts simultaneously.
GreerPICK	The device is designed to individually apply allergen/control extracts.
	MATERIAL
GreerTRACK	thermoplastic polymer.
GreerPICK	thermoplastic polymer.
	PERFORMANCE
GreerTRACK	The device introduces allergens/controls through prick/puncture of the epicutaneous layer of the skin.
GreerPICK	The device introduces allergens/controls through prick/puncture of the epicutaneous layer of the skin. The device can also be used to "scratch" the surface of the skin to introduce the allergen/control.
	STERILITY
GreerTRACK	The product is terminally sterilized by gamma irradiation.
GreerPICK	The product is terminally sterilized by ethylene oxide (ETO) exposure.
	BIOCOMPATIBILITY
GreerTRACK	Epicutaneous contact only, not intended for implantation; the material has been tested to meet USP Class VI criteria.
GreerPICK	Epicutaneous contact only, not intended for implantation; the material has been tested to meet USP Class VI criteria.
	ANATOMICAL SITES
GreerTRACK	The device is intended for the application of allergen/control extracts to the typical sites used in the performance of allergy skin testing (volar surface of the arms and back).
GreerPICK	The device is intended for the application of allergen/control extracts to the typical sites used in the performance of allergy skin testing (volar surface of the arms and back).
	WHERE USED
GreerTRACK	Intended for use in physician clinic setting and/or hospital.
GreerPICK	Intended for use in physician clinic setting and/or hospital

Clinical Performance

To verify the qualitative comparability of the GreerTRACK to the GreerPICK in the performance of the application of skin test materials, both devices were tested side-by-side using histamine as the positive control, and glycerosaline as the negative control. Twelve (12) individuals had a total of 46 applications each of histamine, at both 5 and 0.5 mg/mL, and glycerosaline using the GreerTRACK. The same individuals also had a total of 19 applications of each solution using the GreerPICK. Measurements of the largest and orthogonal diameters for both the erythema and wheal reactions were made and tabulated. The sums of these reactions were calculated as were the overall means and standard deviations for the reactions measured for each test solution.

Conclusions

Results confirm that testing with the GreerTRACK elicits comparable reactions to those elicited by the GreerPICK. As for the GreerPICK, the GreerTRACK can elicit a reaction to a 10 fold dilution of the positive control that is intermediate between the positive and negative controls, and is clearly distinguishable from the reaction associated with the negative control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2000

Mr. Gerald Friesen
Vice President of Quality
Greer Laboratories, Incorporated
639 Nuway Circle, Northeast
P.O. Box 800
Lenoir, North Carolina 28645-0800

Re: K003195
Trade Name: GreerTRACK Skin Testing System
Regulatory Class: Unclassified
Product Code: LDH
Dated: October 11, 2000
Received: October 12, 2000

Dear Mr. Friesen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003195

Device Name: GreerTRACK Skin Testing System

Indications For Use:

The device system is for use in the prick/puncture application of allergen extracts to the epicutaneous layer of the skin in the performance of skin testing for immediate type hypersensitivity reactions in those individuals suspected of having allergies.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucente

Division of De
and General Hosp
510(k) Number K003195

(Optional Format 3-10-98)